SIDLEY

Regulation of Veterinary Medicinal Products

January 6, 2021

VMD updates its import and export of veterinary medicines explainer from January 1, 2021

The Veterinary Medicines Directorate has updated its guidance for the pharmaceutical industry on importing and exporting veterinary medicines from January 1, 2021. See the updated guidance here.

January 6, 2021

VMD updates its guidance on MAH and authorised personnel location

The Veterinary Medicines Directorate has updated its guidance for the pharmaceutical industry on location and other authorised personnel requirements post transition period for existing marketing authorisations and applications submitted after January 1, 2021. See the updated guidance here.

VMD Publishes Guidance on the UK Veterinary Medicines Regulations from January 1, 2020

December 2, 2020

The Veterinary Medicines Directorate ('VMD') explains that the Veterinary Medicines Regulations (VMR) 2013 (Statutory Instrument (SI) 2033), as amended, will remain in force for the regulation of veterinary medicines in the UK beyond the end of the transition period. The VMR will be amended to provide, in effect, 2 sets of VMR having effect in GB and Northern Ireland because NI will remain subject to EU legislation; the GB and NI VMR will remain similar.

The VMD have in place continued recognition for the sites of certain regulatory functions carried out in the EU for batches placed on to the market until January 2023. Many of the requirements beyond this will be included in the new VMRs, which are planned to come into effect in 2022.

The VMD's main objective is to continue to seek future agreements with other countries, including the EU, that benefit veterinary medicine industries in our respective countries. Such reciprocal agreements may be via free trade agreements (FTAs) or mutual recognition agreements (MRAs).

See the guidance **here.**

Guidance for the Pharmaceutical Industry on the Batch Release Scheme for an Immunological Veterinary Medicinal Product to Be Placed on to the UK Market from 1 January 2021

November 25, 2020

From January 1, 2021 a batch of immunological veterinary medicinal product (IMVP) cannot be placed onto the UK market without a batch release request being submitted to the Veterinary Medicines Directorate (VMD). The VMD has issued guidance for the pharmaceutical industry on the batch release scheme for an IMVP to be placed onto the UK market post-Brexit. See the guidance **here.**

Guidance for Veterinary Medicines Manufacturers and Wholesale Dealers in GB on Selling and Supplying Products Placed on the EU and UK Markets before January 1, 2021 and the Evidence You May Need to Provide

SIDLEY

October 30, 2020

The Veterinary Medicines Directorate has published new **guidance** titled "Veterinary medicinal products placed on the EU and NI markets before January 1, 2021."

The guidance covers the following matters:

- **Continued circulation of veterinary medicines placed on the market before January 1, 2021:** Medicine lawfully placed on the UK or EU markets before January 1, 2021 can continue to be made available on these markets and to circulate between the two markets until it reaches the end user (Article 41 of the EU Withdrawal Agreement); this includes medicines moving from GB to NI, NI to EU, and GB to/from EU
    - **"Placed on the market":** Available for sale or supply and there has been a written or verbal agreement (or offer of an agreement) to transfer ownership of the medicine to another legal entity; the placing of a manufacturing order is insufficient to qualify for continued circulation as the medicine must have been manufactured and Qualified Person (QP) certified and released
    - **Medicines with an MA in the country of destination that meet these criteria, which include those already in the supply chain and stored by a wholesaler in the UK or EU (who has been sold or supplied the medicines):** Can continue to move between the UK and EU markets without the need for repeating batch (QC) testing and QP certification/release to meet import or export requirements
- **Medicines placed on the market by 11 p.m. on December 31, 2020:** To qualify for continued circulation between the GB, NI, and EU markets, batches of medicines must be placed on the market which means (i) manufactured; (ii) certified and released by a QP; (iii) made available for sale or supply in the manufacturer's stock management system
    - **Additionally, before 11 p.m. on December 31, 2020:** The medicine must have transferred ownership by sale or supply to another legal entity; or, an offer to either purchase or take ownership of the medicine must have been made to the manufacturer by another legal entity. Where there is an offer, the actual transfer of ownership may take place after 11 p.m. on December 31, 2020
        - This may include transfer of stock for sale or supply to different legal entities in the same company group
- **Evidence for confirming that the veterinary medicine has been "placed on the market" before 11 p.m. on December 31, 2020 before selling or supplying a veterinary medicine from GB to NI or the EU:** Evidence can include providing to the supply chain a written statement to confirm that ownership has transferred by sale or supply to another legal entity, or an offer to take ownership had been made, before 11 p.m. on December 31, 2020; wholesale dealers who hold stock, have (or have offered to) purchase or take ownership of veterinary medicines before 11 p.m. on December 31, 2020, may need to obtain evidence of this from the manufacturer; in some cases, the wholesale dealers' own records may also be acceptable evidence
    - **No need to provide evidence for products moving from the EU to GB:** The Veterinary Medicines Directorate will continue recognise EU batch (QC) testing and QP certification/release until January 2023

- **Product movement between the EU and NI, or from NI to GB:** No import or export requirements

- **Potential scenarios for the GB manufacturer:** For all the scenarios below by 11 p.m. on December 31, 2020 a batch has been QP certified and released and is in the EU, GB or NI manufacturer's warehouse

    - **Scenarios where the medicine has not been placed on the market:**

        - **A batch is 'on hold' in the warehouse inventory system:** The qualifying criteria have not been met because the medicine is not available for sale or supply in the stock management system; EU importation rules will apply for products moving from GB

        - **A batch is marked as available for sale or supply in the warehouse system and no offer has been made by another legal entity to the manufacturer to take ownership of the medicine:** The qualifying criteria have not been met because there is no offer of purchase or ownership transfer

    - **Scenarios where the qualifying criteria have been met:**

        - **A batch is marked as available for sale or supply in the warehouse system, and the ownership of that medicine has been transferred to the affiliate in the EU, GB or NI which is a separate legal entity from the original owner; the medicine is still physically located in the EU, GB or NI manufactures' warehouse:** This medicine has been transferred to a different legal entity and qualifies for provisions under Article 41

        - **A batch is marked as available for sale or supply in the warehouse system, and a separate legal entity to the manufacturer has offered to either purchase or take ownership of the medicine, and the sale or transfer of ownership is not complete:** This medicine has an offer to purchase or take ownership and qualifies for provisions under Article 41

        - **A batch is pre-allocated to supply the NI market; ownership of the medicine is transferred to a different legal entity in the EU:** This medicine has been transferred to a different legal entity and qualifies for provisions under Article 41

        - **A batch is marked as available for sale or supply in the warehouse system, and ownership of the medicine was transferred to a different legal entity before the end of the transition period then ownership is then transferred back to the manufacturer (this second transfer of ownership can take place at any time); the medicine remains in the same physical location throughout:** This medicine had been transferred to a different legal entity and qualifies for provisions under Article 41

            - **The medicines in the above scenarios can be supplied from January 1, 2021 without the need to meet EU importation rules for products moving from GB**

New Guidance for the Veterinary Pharmaceutical Industry on the Detailed Description of Pharmacovigilance System and Qualified Person for Pharmacovigilance from January 1, 2021

October 7, 2020

The Veterinary Medicines Directorate (VMD) has published new **guidance** titled "From January 1, 2021 Pharmacovigilance System and Qualified Person for Pharmacovigilance explainer."

The new guidance covers the following matters:

- **Location of the Qualified Person for Pharmacovigilance (QPPV):**
    - **Centrally authorised Marketing Authorisations (MAs):** The QPPV must be located in the EU for these products to be on the Northern Ireland (NI) market. From January 1, 2021, for existing centralised MAs, you will be offered a GB MA for these products.
    - **GB MAs:** The QPPV can be located anywhere.
    - **MAs issued following Mutual Recognition/decentralised procedures:** These will continue to be issued by the VMD in respect of NI. The QPPV can be located in the EU, NI, or GB, due to interpretation of the requirements of the Northern Ireland Protocol.
    - **UK national MAs (existing) and NI MAs:** The QPPV can be located in the EU, NI, or GB for authorisations issued by the UK in respect of NI due to interpretation of the requirements of the Northern Ireland Protocol. The QPPV for GB MAs can be located anywhere.
- **Pharmacovigilance inspections:** From the January 1, 2021, the VMD will carry out inspections of all Marketing Authorisation Holders (MAHs) for products authorised in the UK; this includes those MAHs located outside of the UK.
    - The VMD will use a risk-based approach to scheduling inspections; risk basis considerations will include last EU inspection date, previous inspection findings, and surveillance intelligence.
    - Inspections will be conducted remotely where possible.
- **Detailed Description of Pharmacovigilance system:** The UK requirement for the Detailed Description of Pharmacovigilance System is under review; the VMD will provide more information as it becomes available.

New Guidance for Imports and Exports of Veterinary Medicines

September 16, 2020

The Veterinary Medicines Directorate has published guidance for the pharmaceutical industry on importing and exporting veterinary medicines from January 1, 2021. See the guidance **here.**